

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

BIOVAIL CORPORATION, *et al.*,

Plaintiffs,

v.

U.S. FOOD & DRUG ADMINISTRATION, *et al.*

Defendant,

and

TEVA PHARMACEUTICALS USA, INC. and
IMPAX LABORATORIES, INC.,

Intervenors-Defendants.

Case No. 06-CV-3355 (RWT)

**JOINT ANSWER OF INTERVENORS TEVA PHARMACEUTICALS USA, INC.
AND IMPAX LABORATORIES, INC.**

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Teva Pharmaceuticals USA, Inc. and
Impax Laboratories, Inc.*

February 20, 2007

Intervenor-Defendants (“Intervenors”) Teva Pharmaceuticals USA, Inc. (“Teva”) and Impax Laboratories, Inc. (“Impax”) respectfully submit the following answers in response to the Complaint filed by Plaintiffs Biovail Corporation and Biovail Laboratories International SRL (“Biovail Corporation” and “Biovail SRL”) on December 18, 2006.

INTRODUCTION

1. The first and third sentences are admitted. The second sentence is admitted, except to the extent it suggests that 21 U.S.C. § 355(j)(5)(B)(iii) would authorize this Court to stay FDA’s approval of Abbreviated New Drug Application (“ANDA”) No. 77-415 pending the expiration of a thirty-month stay. That implication is denied.

2. Intervenors are without information or knowledge sufficient to form a belief as to the truth of the allegation that “Biovail made a good faith determination that the ANDA infringed Biovail’s patent rights,” and therefore deny it. Intervenors deny that Biovail “timely filed an infringement suit.” The second and third sentences are denied.

JURISDICTION AND VENUE

3. Admitted.

4. Admitted, except to the extent this paragraph implies that plaintiffs are entitled to the relief made available by these statutes. That implication is denied.

5. Admitted.

PARTIES

6. The first and third sentences are admitted. Intervenors are without information or knowledge sufficient to form a belief as to the truth of the allegations in the second sentence, and therefore deny them.

7. Admitted.

8. Admitted.

9. Admitted.

STATEMENT OF FACTS

10. Admitted.

11. Admitted.

12. The first sentence is admitted. The second sentence is denied insofar as it suggests that Biovail Corporation is the owner by assignment of the '341 patent, has the right to sue for infringement of that patent, and may recover damages associated with such infringement.

13. Intervenors are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first clause of this paragraph and therefore deny the same. The second clause of this paragraph is admitted to the extent it describes annual sales of 300-mg Wellbutrin XL.

14. Denied to the extent that this paragraph implies that bupropion hydrochloride is the only chemical in Wellbutrin XL extended-release tablets for once-a-day-administration.

15. Denied insofar as it purports to characterize the statutory scheme governing the approval of generic drugs; the statutory scheme is its own best evidence and speaks for itself.

16. Denied insofar as it purports to characterize the statutory and regulatory schemes governing the approval of generic drugs; those statutes and regulations are their own best evidence and speak for themselves.

17. Denied insofar as it purports to characterize the statutory and regulatory schemes governing the approval of generic drugs; those statutes and regulations are their own best evidence and speak for themselves.

18. Denied insofar as it purports to characterize the statutory and regulatory schemes governing the approval of generic drugs; those statutes and regulations are their own best evidence and speak for themselves.

19. Denied insofar as it purports to characterize the statutory and regulatory schemes governing the approval of generic drugs; those statutes and regulations are their own best evidence and speak for themselves.

20. Admitted to the extent this paragraph characterizes the dates on which the Impax “Paragraph IV Certification Notice” was dispatched and received; otherwise denied.

21. Admitted.

22. Intervenor is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of this paragraph and therefore deny the same. The second sentence is denied to the extent it implies that Biovail Corporation or Biovail SRL filed the lawsuit captioned *Biovail Laboratories, Inc. v. Impax Laboratories, Inc.*, No. 05-cv-1085 (E.D. Pa.), on March 7, 2005.

23. Denied to the extent it purports to characterize the complaint filed in *Biovail Laboratories, Inc. v. Impax Laboratories, Inc.*, No. 05-cv-1085 (E.D. Pa.); the complaint is its own best evidence and speaks for itself.

24. Denied, except to the extent it states that *Biovail Laboratories, Inc. v. Impax Laboratories, Inc.*, No. 05-cv-1085 (E.D. Pa.) is currently pending. That allegation is admitted.

25. Intervenor is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.

26. Denied.

27. Admitted, except insofar as it characterizes FDA's approval of ANDA No. 77-415 as "unlawful." That allegation is denied.

28. Admitted, except to the extent it characterizes FDA's approval of ANDA No. 77-415 as "erroneous and unlawful." Those allegations are denied.

CLAIM

29. Intervenor's incorporate their answers to Biovail's allegations in paragraphs 1 through 28 as though fully answered herein.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

The remainder of the Complaint is plaintiffs' prayer for relief, to which no answer is required. Insofar as an answer may be required, Intervenor's deny that plaintiffs are entitled to the requested relief or any relief whatsoever.

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

WHEREFORE, Intervenor respectfully request that the Court enter judgment in their favor, dismiss the Complaint with prejudice, and award Intervenor their costs, expenses, attorneys' fees, and such additional relief as the Court may deem appropriate.

Respectfully submitted,

_____/s_____
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February 20, 2007

CERTIFICATE OF SERVICE

The undersigned certifies that on this 20th day of February 2007, a true and correct copy of the foregoing Answer was served via ECF filing as follows:

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